EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

COM(2023)224 + Annex

Explanatory Memorandum for EU Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

With

SEC(23)173: Regulatory Scrutiny Board Opinion
SWD(23)120: Subsidiarity Grid
SWD(23)121: Impact Assessment
SWD(23)122: Executive Summary of the Impact Assessment

Submitted by the Intellectual Property Office (IPO), an executive agency of the Department for Science, Innovation & Technology on 14/6/2023.

SUBJECT MATTER

Patents provide a temporary exclusive right which incentivises innovation and investment required to develop new technologies, including new medicines. Without this incentive, businesses would be less likely to invest in developing new technologies.

A patent owner can stop others from copying their innovation without their permission. However, many patent owners enter into voluntary agreements with other businesses to allow them to use their innovation (for example to allow them to manufacture their patented medicine). These voluntary agreements can increase manufacturing capacity for a new technology and allow other businesses to benefit from the patent owner's technical knowledge and experience.

Patent systems in the UK and other countries also include a safety net for use in situations where voluntary agreements cannot be reached, including in emergency situations. This safety net allows governments to issue a 'compulsory licence' to a third party to allow them to use or manufacture a patented technology without the consent of the patent owner, as long as certain requirements are met.

Compulsory licences generally only allow use primarily for the domestic market. However, in certain circumstances they can also be used to allow production of

medicines for export to countries with public health problems where those countries do not have manufacturing capability to produce the medicines that they need. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) sets out the requirements that must be met when a compulsory licence is issued.

Patents are territorial, and there is currently no harmonisation of EU compulsory licensing laws for supply to the domestic EU market. National EU compulsory licensing laws do not allow products manufactured under a compulsory licence in one Member State to be supplied to another Member State (or they can only be supplied in limited quantities).

The EU proposals would provide a new EU-wide compulsory licensing approach for use in crisis situations and for supplying countries with public health problems.

The proposal is noted to have two main objectives. First, it aims to enable the EU to rely on compulsory licensing in the context of EU crisis legislation. Second, it introduces an efficient compulsory licensing scheme, with appropriate features, to allow a swift and appropriate response to crises, with a functioning Internal Market, guaranteeing the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

SCRUTINY HISTORY

There is no relevant recent scrutiny history.

MINISTERIAL RESPONSIBILITY

Secretary of State for the Department for Science, Innovation, and Technology Chloe Smith MP holds responsibility for the relevant Department.

Viscount Camrose, Parliamentary Under Secretary of State (Minister for AI and Intellectual Property) has a key interest in this area.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Intellectual property is a reserved matter.

The devolved governments have been consulted in the preparation of this Explanatory Memorandum and had no comments.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the EU ('TFEU').

ii. Voting Procedure

The EU voting procedure is expected to involve qualified majority voting.

iii. Timetable for adoption and implementation

The proposed Regulations still need to be discussed and agreed by the European Parliament and the Council of the European Union prior to implementation. No further information on timings is available at this stage.

POLICY IMPLICATIONS

Patent rights are territorial, including in EU Member States, and the EU currently has a patchwork of different national systems for compulsory licensing. The EU proposals would provide a new EU-wide compulsory licensing approach for use in crisis situations. This new EU compulsory licensing approach would have two main parts:

1) A new EU-wide compulsory licence (granted by the European Commission) for supplying the EU domestic internal market in a crisis or emergency situation. This would provide a single procedure to grant an EU-wide compulsory licence rather than the current patchwork of national compulsory licensing laws among the 27 EU Member States.
2) An EU-wide compulsory licence for producing medicines for export to countries with public health problems where those countries do not have manufacturing capability to produce the medicines they require themselves.

Part 1) would be implemented by a new EU Regulation which would establish the proposed EU-wide compulsory licensing system for crisis management at EU level, whilst leaving national compulsory licensing schemes in Member States untouched. This new Regulation would not apply to Northern Ireland as it is not listed in the Windsor Framework.

Part 2) of the compulsory licensing proposal would be implemented through amendments to the existing EU Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

The EU-wide compulsory licence appears to permit both domestic manufacturing in a single country and cross-border manufacturing processes between multiple countries[1].

Regulation (EC) 816/2006 applies to Northern Ireland by virtue of the provisions set out in the Windsor Framework[2]. Furthermore, the Windsor Framework also includes provisions which mean that any amended version of Regulation (EC) 816/2006 would also apply to Northern Ireland[3], unless the derogation in the Windsor Framework[4] (the "Stormont Brake") were utilised.

This means that an EU-wide compulsory licence issued by the EU under an amended version of Regulation (EC) 816/2006 may apply in Northern Ireland, though impact on the NI market is expected to be limited, as explained further below.

The existing UK patent system (like those of many other countries) already includes compulsory licensing provisions and details the processes to invoke them. These existing UK provisions are considered to be appropriate and there are no plans to amend them at this time.

The EU proposals are not expected to impact on Northern Ireland's participation in the UK's Free Trade Agreements or Northern Ireland's participation in UK Common Frameworks.

The UK Government has not had any substantive engagement with the EU in relation to the development of the proposal. We intend to seek further information from the EU in due course on this Regulation.

The EU appears to be putting forward these proposals as an internal market measure for crisis situations and for supplying countries with public health problems more efficiently through the EU internal market. While this may increase the ease with which the compulsory licensing mechanism can be invoked in the EU, compulsory licensing is a last resort and rarely used mechanism. At the time of writing, the World Trade Organisation website[5] records only two notifications of requests for compulsory licences in relation to the manufacture of pharmaceutical products for export to countries with public health problems. Consequently, if the proposals were to apply, we would expect a limited impact on the Northern Ireland market. However, the Government is continuing to analyse potential practical implications of these

[1] Recital 37 of the proposed EU Regulation suggests cross-border manufacturing COM_2023_224_1_EN_ACT_part1_v11.pdf (europa.eu)

[2] Article 5(4) and Annex 2 (item 7)

[3] Article 13(3) of the Windsor Framework

[4] Article 13(3)(a) of the Windsor Framework

[5] WTO website: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%20@Symbol=%20ip/n/8/*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#

proposals, and will continue to monitor the proposals as discussions develop in the European Parliament and the Council of the EU.

CONSULTATION

The UK Government has not been involved in the EU's consultations for the proposal or the development of the EU's impact assessment. The Government has not prepared a separate impact assessment about the proposal.

FINANCIAL IMPLICATIONS

The proposal is not expected to have specific financial implications for the UK.

MINISTERIAL NAME AND SIGNATURE

Viscount Camrose

Parliamentary Under Secretary of State (Minister for AI and Intellectual Property)

Department for Science, Innovation and Technology